

Applicant: Garrity et al.
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Remarks

I. INTRODUCTION

Claims 1-43 and 66-84 were pending. Claims 42, 43, and 66-84 have been withdrawn from consideration. By way of this response, claims 1-3, 11-12, 15-20, 23-24, and 40 have been amended, claims 13-14, 21, 42-43, and 66-84 have been cancelled, and claim 85 has been added. Support for the amendments to the claims may be found in the specification as originally filed, and care has been taken to avoid adding new matter. Accordingly, claims 1-12, 15-20, 22-41, and 85 are pending.

The claims have been amended to address the rejections identified in the Office Action. The specification has been amended to address the use of trademarks, to add a Brief Description of the Drawings, and to address the removal of the figures of Table I. The drawings have been amended to reflect the addition of the new drawings, which are identical to Table I.

An executed Supplemental Declaration is enclosed herewith to address the deficiencies of the original Declaration.

II. DRAWINGS

As indicated above, Applicant has amended the application to include the enclosed drawings which are identical to Table I that was originally included in the application.

III. OATH/DECLARATION

As indicated above, Applicant encloses herewith an executed Supplemental Declaration.

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IV. SPECIFICATION

As indicated above, Applicant has amended the specification to address the use of trademarks, and to address the addition of the drawings.

V. CLAIM REJECTION(S)

Claims 1-41 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 1-6, 12-18, 20-22, and 41 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kobayashi et al. in view of the Instruction Manual of Incstar Corporation. Claims 19-23 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kobayashi et al. in view of the Instruction Manual of Incstar Corporation and further in view of Atkinson et al. Claims 7, 25-27, and 38-40 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kobayashi et al. in view of the Instruction Manual of Incstar Corporation and further in view of DeLuca et al. Claims 8-11 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kobayashi et al. in view of the Instruction Manual of Incstar Corporation. Claims 28-40 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kobayashi et al. in view of the Instruction Manual of Incstar Corporation and further in view of DeLuca et al. and further in view of Nargessi et al.

The Office Action indicates that kits comprising at least NaOH, cyclodextrin, and sodium salicylate appear to be allowable. The Office Action also indicates that claim 24 would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claim.

Regarding the rejections of claims 1-41 under 35 U.S.C. § 112, second paragraph, claim 1 has been amended by deleting the terms "facilitates" and "vitamin D component binding protein"; claim 2 has been amended by deleting the "use" language; claim 3 has been amended by deleting "and mixtures thereof"; claim 12 has been amended by deleting the term "substantially"; claim

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15 has been amended by deleting the term "randomly"; claim 19 has been amended by deleting the term "including sodium salicylate"; and claim 21 has been cancelled.

In view of the above, Applicant submits that the rejections have been overcome, and that the present claims are definite under 35 U.S.C. § 112, second paragraph.

Regarding the rejections of the claims under 35 U.S.C. § 103, the claims have been amended to indicate that the kit includes a cyclodextrin, a salicylate, and an aqueous base component selected from the group consisting of NaOH and KOH. As indicated in the Office Action, such kits are allowable over the cited references.

In addition, Applicant submits that one of ordinary skill in the art would not be motivated to combine the teachings of Atkinson et al. with Kobayashi et al. in view of the Instruction Manual of Incstar Corporation at least because the teachings of the references are from nonanalogous arts. While Kobayashi et al. is researching the detection of a vitamin D metabolite from samples, Atkinson et al. discloses the detection of a salicylate, such as aspirin, from a sample. The two are not even related. Applicant also disagrees that Atkinson et al. teaches that salicylate compositions are important in drug evaluation of biological fluids. The passage identified by the Examiner states that the level of salicylate compounds in biological fluids is required to be estimated when a patient is suffering from a drug overdose, for example. In other words, the salicylate is being measured, and is not being used in an assay for some other component present in a biological sample.

Applicant also submits that the Examiner has not met the burden of proof to establish that one of ordinary skill in the art would modify the teachings of the art by using NaOH and KOH in a releasing composition, as recited in claims 8-11. The Office Action states that NaOH and KOH are equivalents for an aqueous base solutions, but the Office Action fails to indicate what aqueous base solutions are equivalents. The Office Action states that Kobayashi discloses aqueous bases, such as bovine serum albumin (BSA) and ovalbumin (OVA). While not conceding to the Examiner's characterization of BSA and OVA as aqueous bases, Applicant

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submits that NaOH and KOH are not equivalents of either BSA or OVA. To support this, Applicant notes that the Aldrich list of Volumetric Solutions, which the Examiner has identified, does not indicate that NaOH and/or KOH is an equivalent of BSA or OVA, let alone that BSA or OVA is an aqueous base. Accordingly, Applicant submits that the rejections of claims 8-11 under 35 U.S.C. § 103 cannot be maintained in view of the remarks made in the Office Action.

Nevertheless, the present claims now include components which the Examiner has indicated to be allowable. In view of the above, Applicant submits that the present claims are unobvious from and patentable over the cited references, alone or in combination, under 35 U.S.C. § 103.

VI. CONCLUSION

In conclusion, Applicant has shown that the present specification is in proper form, that the present claims satisfy the requirements of 35 U.S.C. § 112, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-12, 15-20, 22-41, and 85 are allowable. Applicant requests the Examiner to pass the above-identified application to issuance at an early date.

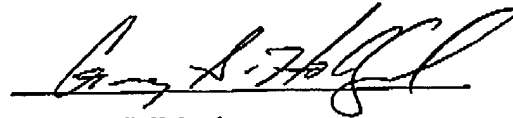
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If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

Date: _____

10/15/03



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